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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,565

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Roberto Oliva

OLIVA1

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EXAMINER

YOUNG, RACHEL T

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,565	<b>Applicant(s)</b> OLIVA, ROBERTO	
	<b>Examiner</b> RACHEL T. YOUNG	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/17/07</u> .                                                 | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Preliminary Amendment***

1. This office action is responsive to the preliminary amendment filed on 4/17/07. As directed by the amendment: claims 4 and 7 have been amended. No claim was added or cancelled. Thus, claims 1-7 are presently pending in the application.

### ***Foreign Priority***

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Italy on 3/18/2004. It is noted, however, that applicant has not filed a certified copy of the MO2004A000060 application as required by 35 U.S.C. 119(b).

### ***Drawings***

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Reference number "3c" on Page 3, ll. 29 and throughout the rest of the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

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informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "comprising", "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

5. The abstract of the disclosure is objected to the terms "the 5 outside" in line 4, and "10 making" in line 10 of the abstract are confusing. Correction is required. See MPEP § 608.01(b).

6. The disclosure is objected to because of the following informalities: Page 2, line 20 recites "allows to overcome", which should be changed to --overcomes--. Page 2, line 23 recites "to inhale", which should be changed to --inhalation of--.

Appropriate correction is required.

### ***Claim Objections***

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7. Claims 1-2, 4, 7 and 9 are objected to because of the following informalities:

Claim 1, line 4 recites "the outside", which lacks proper antecedent basis. Claim 1, line 6 recites "respect o said", which should be changed to --respect **to** said--. Claim 2, lines 3, 7, 10, and 12 recite "3c", which is not labeled in the drawings. Claim 2, line 4 recites "axis (s)", which should be changed to --axis (x)--. Claim 2, line 8 recites "open said", which should be changed to --open **to** said--. Claim 4, line 3 recites "bottom wall", which should be changed to --bottom **of** wall--. Claim 7, line 2 recites "said first and second protrusions (8, 9)". The "second protrusions" lacks antecedent basis. Claim 7, line 5 recites "second outlet (3)", which should be changed to --second outlet (3b)--. Claim 9, line 2 recites "3c", which is not labeled in the drawings. Claim 9, line 3 recites "end a portion", which should be changed to --end **and** a portion--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4 and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohki et al. (2002/0033177 A1).

As to claim 1, Ohki discloses an inhaler (Fig. 13) for preparations in powder form ("powdered medicines" 16) (Fig. 13), characterized in that it comprises a first body

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("medical powder storage cylindrical member" 43), which is provided with an inhaling channel ("inhalant port" 3, "medical powder diffusion chamber" 4, "outflow air passageway" 6, "outflow outlet port" 44c, "cylindrical fit hole" 42) (Fig. 13), and a second body ("medicator body" 41) (Fig. 13), which is provided with at least one reservoir ("medical powder storage chamber" 47) (Fig. 13), which is open toward the outside (when body 43 is removed, 47 is open to the outside Fig. 13) and is preset to contain at least one dose of preparation in powder form ("powdered medicines" 16) (Fig. 13), the first body being associated with said second body (Fig. 13) and being movable with respect to the second body (Fig. 13) (Page 7, ¶ 87) between a first position (Fig. 13), at which it closes the reservoir (6 and 44c are not aligned Fig. 13), and a second position (Fig. 15), at which at least one connection is open between the reservoir and the inhaling channel (6A and 44c are aligned and open to 47 in Fig. 15), making the dose of preparation in powder form available for inhaling (Fig. 15) (Page 7, ¶ 87).

As to claim 2, Ohki teaches that the first body ("medical powder storage cylindrical member" 43) has a longitudinal axis (x) (Fig. 13) and is provided longitudinally with a through inhaling channel ("inhalant port" 3, "medical powder diffusion chamber" 4, "outflow air passageway" 6, "outflow outlet port" 44c, "cylindrical fit hole" 42) (Fig. 13), which has at least one lateral outlet ("radial passage" 6A) (Fig. 13), the longitudinal extension of which is perpendicular to the longitudinal axis (x) of the first body (Fig. 13), the second body ("medicator body" 41) (Fig. 13) is provided with a receptacle ("cylindrical fit hole" 42) (Fig. 13), in which the first body is inserted at least for the part of its longitudinal extension on which the lateral outlet is arranged (Fig. 13),

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the reservoir ("medical powder storage chamber" 47) (Fig. 13), preset to contain a dose of preparation in powder form with which the second body is provided ("powdered medicines" 16) (Fig. 13), is open the receptacle (Fig. 13), the first body can rotate about its own longitudinal axis (x) with respect to the second body (Page 7, ¶ 87) (Fig. 13) between a first position (Fig. 13), at which the lateral outlet ("radial passage" 6A) (Fig. 13) of the inhaling channel does not face the opening of the reservoir (Fig. 13) and said reservoir is not connected to the inhaling channel (6 and 44c are not aligned Fig. 13), and a second position (Fig. 15), in which the lateral outlet of the inhaling channel faces the opening of the reservoir (6A and 44c are aligned and open to 47 in Fig. 15) and the reservoir is connected to the inhaling channel (Fig. 15).

As to claim 3, Ohki teaches that the inhaling channel has, at its ends, a first outlet ("inhalant port" 3) (Fig. 13) and a second outlet (right end opening of cylindrical fit hole 42 in Fig. 13 and 15, where cylindrical portion 44 enters and the space between disk shaped knob portion 45 and 41 in Fig. 15), which are arranged approximately at right angles to the longitudinal (x) of the first body (Fig. 13 and 15), the end at which the second outlet is arranged being in contact with an end wall ("disk shaped knob portion" 45) (Fig. 13) of the receptacle ("cylindrical fit hole" 42) (Fig. 13) that is perpendicular to the longitudinal axis (x) (Fig. 13).

As to claim 4, Ohki teaches that the second body is provided with a through channel ("inflow air passageway" 5) (Fig. 15), which has a first outlet (bottom right outlet opening to atmosphere) (Fig. 15) arranged at the bottom of wall ("disk shaped knob portion" 45) of the receptacle ("cylindrical fit hole" 42) (Fig. 13) and a second outlet

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("radial passage" 5B) (Fig. 13) arranged on the outer surface of the second body (Fig. 13), the first outlet of the through channel being arranged in a position in which it faces the second outlet (Fig. 15) of the inhaling channel at least at the second position of the first body (Fig. 15).

As to claims 8-9, Ohki teaches that the second body is provided with a through hole (right end opening of cylindrical fit hole 42 in Fig. 13 and 15, where cylindrical portion 44 enters) (Fig. 15), which faces the opening of the reservoir (Fig. 15), the lateral outlet and the second outlet of the inhaling channel (3) form a single opening that lie between one end ("disk shaped knob portion" 45) and a portion of the lateral surface of the first body ("engaged protrusion portion" 44A) (Fig. 13).

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohki et al. in view of Anderson et al. (6,065,472).

As to claim 5, Ohki teaches the above limitations, but is silent regarding that the inhaling channel has at least one first protrusion, which protrudes transversely to the longitudinal axis (x) of the first body from the lateral surface of the inhaling channel toward the inside of said inhaling channel. However, Anderson teaches that the



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inhaling channel has at least one first protrusion ("penultimate baffle" 26) (Fig. 4), which protrudes transversely to the longitudinal axis (x) of the first body from the lateral surface of the inhaling channel toward the inside of said inhaling channel (Fig. 4). It would have been an obvious design consideration to one of ordinary skill in the art at the time the invention was made to place Anderson's "penultimate baffle" 26 along Ohki's "medical powder storage hole" 46 of the Ohki's first body "medical powder storage cylindrical member" 43, as taught by Anderson, for the purpose of providing a way to break down the medicament to provide better inhalation to the user.

As to claim 6, the modified Ohki's inhalator has everything as claimed as well as the second protrusion (Anderson "final baffle" 25) (Fig. 4), which protrudes transversely to the longitudinal axis (x) of the first body from the lateral surface of the inhaling channel toward the inside of said inhaling channel (Anderson Fig. 4), the second protrusion being spaced with respect to the first protrusion toward the longitudinal axis (x) of the first body (Anderson Fig. 4) and being arranged opposite with respect to a central plane of the inhaling channel (Anderson Fig. 4). It would have been an obvious design consideration to place Anderson's "penultimate baffle" 26 and "final baffle" 25 along the modified Ohki's "medical powder storage hole" 46 of the modified Ohki's first body "medical powder storage cylindrical member" 43, as taught by Anderson, for the purpose of providing a way to break down the medicament to provide better inhalation to the user.

As to claim 7, Ohki's modified inhalator teaches the above limitations, but is silent regarding that the first and second protrusions have at least one surface that is inclined

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and blended with the lateral surface of the inhaling channel, the surfaces that are inclined and blended with the lateral surface of the inhaling channel being directed toward the second outlet of the inhaling channel. However, Anderson teaches that the first and second protrusions have at least one surface that is inclined and blended with the lateral surface of the inhaling channel (Fig. 4), the surfaces that are inclined and blended with the lateral surface of the inhaling channel being directed toward the second outlet of the inhaling channel (Fig. 4). It would have been an obvious design consideration to place Anderson's "penultimate baffle" 26 and "final baffle" 25 along the modified Ohki's "medical powder storage hole" 46 of the modified Ohki's first body "medical powder storage cylindrical member" 43, which would then direct the baffles toward the modified Ohki's second outlet (right end opening of cylindrical fit hole 42 in Fig. 13 and 15, where cylindrical portion 44 enters and the space between disk shaped knob portion 45 and 41 in Fig. 15) of the modified Ohki's inhaling channel, as taught by Anderson, for the purpose of providing a way to break down the medicament to provide better inhalation to the user.

### ***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Brown et al. (6,983,748 B2) to a dry powder inhaler that requires rotation of a member to release a dose of medicament to an inhalation channel and Braithwaite et al. (2003/0116157 A1) to an inhaler with a reservoir and metering member that delivers dry powder medicament to a delivery passage upon rotation. Any

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inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL T. YOUNG whose telephone number is (571)270-1481.

The examiner can normally be reached on mon-thurs 7 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RACHEL T YOUNG/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771